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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,264	12/28/2005	Yasuko Nakagawa	082368-004000US	4474

20350 7590 06/30/2008  
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EXAMINER
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KOLKER, DANIEL E

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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06/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,264	<b>Applicant(s)</b> NAKAGAWA ET AL.	
	<b>Examiner</b> DANIEL KOLKER	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 29-35 and 38 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-35 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application        |
| Paper No(s)/Mail Date <u>12/28/05</u>  | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignments</u> |
| <u>1/30/06, 2/10/06, 10/10/07, 12/28/07, 1/24/08, 3/3/08.</u>                          |  |



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### **DETAILED ACTION**

1. The remarks and amendments filed 4 April 2008 have been entered. Claims 29 – 35 and 38 are pending.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group I (claims 29 – 35 and 38) in the reply filed on 4 April 2008 is acknowledged.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

4. The information disclosure statements have been considered.

On the IDS filed 28 December 2005, applicant has indicated that 4 pages are present (note the pages were listed as "1 of 4" and "2 of 4"). Only 2 IDS pages are present in the case. If others were present, please provide additional copies.

### ***Claim Objections***

5. The listing of claims filed 4 April 2008 does not list claims 39 – 40. These claims are presumed to be canceled, since they were not part of the elected group and do not presently appear in the case. Applicant is reminded that a complete listing of claims should list the status of all claims, even those which have been canceled.

### ***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 38 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a reagent comprising an antibody, which is a product of nature. Antibodies are made by animals upon exposure to the relevant antigen and occur within the animal; no hand of man is required to make antibodies. In order to distinguish

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the claimed invention from those antibodies residing within animals and to overcome this rejection, it is suggested that applicant amend claim 38 to recite "An isolated antibody" or "A reagent... comprising an isolated antibody". While claim 38 is drawn to a reagent rather than an antibody *per se*, the only structural element recited in the claim is an antibody.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 – 35 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies which bind to SEQ ID NO:3 or 4 and methods of selecting cells by contacting the cells with such antibodies, does not reasonably provide enablement for the full scope of antibodies as broadly recited in both the product and methods claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

In the instant case, the nature of the invention is a series of antibodies (claim 38) that bind to proteins with some degree of structural similarity to either SEQ ID NO:3 or 4 as well as methods of using those antibodies to select cells (claims 29 - 35). The specification discloses (p. 4 lines 2 - 4, as well as Figure 14 and p. 39 lines 7 – 25) that an antibody raised against an extracellular fragment of 65B13 protein is specifically expressed on dopaminergic neuron precursors. While the specification fails to disclose the exact sequence used to generate the antibody, the specification does indicate that there is substantial identity between two 65B13 variants. As shown in Figure 5, SEQ ID NO:3 and 4 are identical with the exception of an

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insertion of about 50 amino acids in the former. Thus it is reasonable that the skilled artisan could determine how to make and how to use antibodies that bind to these sequences, and it is reasonable that antibodies to either SEQ ID NO:3 or 4 could be used to purify dopaminergic neuron precursor cells, as recited in claims 29 and 32.

However, independent claims 29, 32, and 38 each encompass considerably broader subject matter than what is enabled by the specification. For example, parts (ii) - (v) of each claim encompasses antibodies that bind to proteins encoded by a nucleic acid complementary to those nucleic acids that encode SEQ ID NO:3 or 4. While antibodies that bind to SEQ ID NO:3 or 4 are certainly useful, the specification does not disclose to the public how to use those antibodies that bind to proteins encoded by the complementary strand of nucleic acid. As DNA is comprised of two antiparallel strands, the protein encoded by the antisense (complementary) strand will be entirely different from encoded by the sense strand. There will be no structural, and therefore no functional, similarity between the two proteins. See for example Alberts (1994. Molecular Biology of the Cell, pp. 104 – 111, cited on IDS filed 3 March 2008), who teaches that DNA is made of complementary strands and that the protein sequence is determined by the nucleic acid sequence (p. 104). Alberts also teaches that the shape of a protein determines its function (p. 111). As the specification fails to provide guidance as to the function of the protein encoded by the strand complementary to nucleic acids that encode SEQ ID NO:3 or 4, the skilled artisan would have to determine, on his or her own, how to use this protein and then determine how to use the antibodies that bind to it.

Additionally, part (iv) of each of the claims allows for there to be a large number of insertions, deletions, or substitutions. Likewise, part (v) of claims 29, 32, and 38 reads on antibodies to proteins encoded by different nucleic acids; there is no requirement for any degree of conservation or identity at the protein level. Claims 29, 32, and 38 (parts (iv) and (v)) allow that the protein bound by the claimed antibodies have any possible number of deletions, insertions, or substitutions of amino acid residues.

The specification fails to disclose to the skilled artisan how to use the antibodies which bind to these structurally and functionally unrelated proteins. As the protein sequence varies further and further from that of SEQ ID NO:3 or 4, the antibodies become less and less likely to bind to those proteins, and therefore less and less likely to accomplish the steps of purification and selection set forth in claims 29 and 32. Thus the artisan would have to determine, on his or her own, how to use the antibodies encompassed by claim 38 and how to accomplish the

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methods set forth in claims 29 and 32 with antibodies that do not bind to SEQ ID NO:3 or 4. Given the paucity of guidance provided in the specification, the large degree of experimentation required by the artisan to determine this would clearly be undue.

8. Claims 29 – 35 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 38 is drawn to an antibody which binds to a protein "with a deletion, insertion, substitution, or addition of one or more amino acids in the amino acid sequence of SEQ ID NO:3 or 4"; independent claims 29 and 32 are drawn to methods of using these antibodies. The specification discloses SEQ ID NO:3 and 4 but does not disclose the structure of proteins that have an unlimited number of possible substitutions from these disclosed sequences, or antibodies that bind to such variants, or methods of selecting dopaminergic cells by using such antibodies. The structure of the variable region of an antibody is defined, in part, by the protein to which it binds, so in order to describe the claimed antibodies (and methods of using them) the specification must describe either the structure of the binding region itself or alternatively the proteins to which the antibodies bind. In the case of elements (ii) - (iv) of claims 29, 32, and 38, the claims allow for the antibody to bind to a protein encoded by the nucleic acid complementary to those nucleic acids that encode SEQ ID NO:3 and 4. The specification does not disclose the structure of those nucleic acids, does not disclose the structure of the proteins encoded by them, which would be expected to be totally unrelated to SEQ ID NO:3 or 4 as described in the scope of enablement rejection above, and does not describe the structure of the claimed antibodies. Additionally, elements (iv) and (v) of the independent claims only require a certain degree of identity or hybridization at the nucleic acid level; there is no requirement that the protein encoded by the nucleic acids recited in these have any structural relation to SEQ ID NO:3 or 4. The claims encompass antibodies which bind to proteins encoded by frame-shifting mutations; neither the mutations at the nucleic acid level, the amino acid level, nor the claimed antibodies have been described to the skilled artisan in the specification.

Here, the skilled artisan cannot visualize those antibodies within the scope of the claims, as the disclosure fails to describe either the claimed antibodies or the proteins to which they

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bind. The specification does not disclose those structural elements which are common to all members of the claimed genera of antibodies, and does not disclose the structural elements common to all proteins to which the antibodies bind. Thus, the specification fails to adequately describe the claimed antibodies or methods of using them.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 – 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "stringent conditions" in claims 29, 32, and 38 part (v) is a relative term which renders the claim indefinite. The term "stringent conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no requirement that any particular degree of stringency be used in finding the nucleic acids which encode polypeptides that bind to the claimed antibodies. Thus the skilled artisan could not determine which antibodies are within the scope of the claims and which are beyond the scope of the claims. Thus independent claims 29, 32, and 38 are each indefinite. The remaining claims are rejected because they depend from a rejected base claim and are not limited to that subject matter which is definite.

10. Claims 32 – 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claim 32 is confusing, because the steps recited in the claim will not allow the skilled artisan to accomplish the goal stated in the preamble. The preamble states that it is "[a] method of producing a dopaminergic neuron precursor cell", which indicates that a cell is actually made by this method. However, no steps of manufacturing cells, or of causing cells to differentiate are recited in the body of the claim. Rather, the claim instructs the artisan to perform certain steps which could result in an antibody binding to a dopaminergic cell. If the step recited in claim 33 were also performed, the method would be one of selecting a cell, but would not be one of producing a cell. Because the steps set forth in the body of the claim do



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not allow the skilled artisan to accomplish the stated method, it is unclear whether claim 32 is a method of selecting a cell or a method of producing a cell. Claims 33 – 35 depend from rejected claim 32 but are not limited to subject matter which is definite. It is noted that independent claim 29 is not subject to this rejection, as the steps of selecting a cell from a heterogeneous population will accomplish the stated goal of that claim, “[a] method of selecting a dopaminergic ... cell”.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Carulli (WO 01/98630, published 27 December 2001, cited as reference AB on IDS filed 10 February 2006).

Carulli teaches a 708 amino-acid protein referred to as either gp354 or SEQ ID NO:8; the protein and encoding nucleic acid are set forth in Figure 7 from the reference. As indicated by the enclosed sequence alignment, the prior art protein is 85.6% identical to applicant's SEQ ID NO:3 and differs from that sequence by 40 conservative substitutions, 66 mismatches, 5 deletions, and two gaps. Carulli also teaches antibodies to this protein; see p. 63 line 23 – p. 73 line 19, particularly p. 64 lines 8 – 11. Thus the reference teaches antibodies within the scope of claim 38, particularly parts (iii) – (v). Therefore claim 38, drawn to antibody products, is anticipated.

Claim 32 is drawn to a method wherein the sole step is contacting a cell sample with the recited antibody. The reasons why the antibody is anticipated are set forth in the previous

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paragraph. At p. 89 lines 19 – 24, Carulli teaches contacting a fluid or a tissue sample, which is a cell sample, with the antibody. Thus the reference teaches every step recited in the claim. Claim 35 is anticipated as the antibody necessarily has an affinity for the extracellular region. It is noted that no particularity is recited in the claim, only that some affinity exist. Even if the antibody from Carulli has a very weak affinity for this region, it is “an affinity” as recited in claim 35.

12. Claims 32, 35, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Sun (2003) Genomics 82(2):130-142. Note the cover page of the reference indicates it was available online 11 June 2003.

Sun teaches a protein called Kirrel2. As evidenced by the enclosed sequence alignment; the protein is 99.7% identical to applicant's SEQ ID NO:3. Sun also teaches antibodies to this protein; see p. 132 final paragraph – p. 134 second column line 5. Given the very high sequence homology between Sun's protein and that of applicant's SEQ ID NO:3, the antibodies from Sun are within the scope of claim 38, thus this specific antibody anticipates the generic claim. Claim 32 is drawn to a method wherein the sole step is contacting a cell sample with the recited antibody. The reasons why the antibody is anticipated are set forth in the previous paragraph. At p. 133 first complete paragraph and Figures 5 and 7, Sun teaches contacting cells with the antibodies. As the step of contacting is the only step recited in claim 32, the reference anticipates this claim as well. Claim 35 is anticipated as the antibodies have an affinity for the extracellular region; in fact they were raised against this region (see paragraph spanning pp. 132 – 133).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

13. Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Baker (U.S. Patent Application Publication 2002/0127584, published 12 September 2002, cited as reference 2 on IDS filed 3 March 2008).

Baker teaches SEQ ID NO:584 and antibodies thereto. See for example p. 22 paragraph [0610], Figure 584. Baker's protein of SEQ ID NO:584 is 708 amino acids long, and is 85.6% identical to applicant's SEQ ID NO:3 and contains many stretches of identity over well

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more than 8 amino acids; see enclosed alignment. Baker refers to this protein as “PRO19646” (see paragraph [0610]) and teaches the public how to make antibodies against all “PRO” polypeptides, including this one. See pp. 51 - 55 for a description of how to make and how to use the antibodies; see also claim 11, which specifically claims antibodies to the disclosed sequences. Given the very high degree of homology between instant SEQ ID NO:3 and Baker’s SEQ ID NO:584, and given that the claimed antibodies need bind only to 8 amino acids and that there are many long stretches of identity between the two sequences, the prior art antibodies meet the limitations of claim 38.

14. Claim 38 is rejected under 35 U.S.C. 102(e) as being anticipated by Goddard (U.S. Patent 7,304,145, issued 4 December 2007, filed 16 July 2002, and claiming benefit of older applications filed between 2001 – 2002, cited as reference 3 on IDS filed 3 March 2008).

Goddard ‘145 patent issued from a continuing application of 10/052586, which is the basis of the Baker 2002/0127584 reference above. Thus the disclosure of Goddard ‘145 patent is identical to that of the Baker reference. The reasons why Goddard anticipates claims 5 and 10 are the same as why Baker anticipates these claims. Additionally, Goddard ‘145 explicitly claims the antibodies that bind to her SEQ ID NO:584, i.e. those which structurally meet the limitations of claim 38. See Goddard, claims 1 – 5.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Additionally since the patent claims the same patentable invention as is now claimed in claim 38, a declaration under 37 CFR 1.131 cannot be used to antedate the reference.

15. Claims 29, 31 - 33, 35, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen (U.S. Patent Application Publication 2004/0241170, published 2 December 2004, PCT filed 26 August 2002, claiming benefit of a U.S. provisional application filed 24 August 2001).

Jensen teaches a protein called FA1 and antibodies to same; see for example abstract and paragraph [0085]. While the protein does not share a high degree of identity with either SEQ ID NO:3 or 4, independent claims 29, 32, and 38 each allow for antibodies that bind to proteins that have an unlimited number of possible substitutions from the disclosed sequences;

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see for example element (iv) of each of these claims. Thus the antibodies taught by Jensen are within the scope of the products claimed in claim 38 and recited in the methods of claims 29 and 32. Jensen also teaches contacting cell populations including neuronal progenitor cells with the FA1 antibodies and subsequently selecting those cells which have bound to the antibody; see for example paragraphs [0085] - [0086]. Note the latter paragraph specifically teaches isolation of the dopaminergic cells from the substantia nigra. Thus, the reference anticipates each of claims 29, 32, and 33. Claims 31 and 35 are included in this rejection as the antibody necessarily has an affinity for the extracellular region. It is noted that no particularly is recited in the claim, only that some affinity exist. Even if the antibody from Jensen has a very weak affinity for this region, it is "an affinity" as recited in claims 31 and 35.

16. Claims 29 – 35 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Buck (U.S. Patent Application Publication 2003/0109039, published 12 June 2003, filed 11 July 2002, claiming benefit of previous-filed applications in 1999 and 2001).

Buck teaches antibodies which bind to CD133 and use of those antibodies to purify precursor cells which develop into dopaminergic cells. Since the antibodies encompassed by part (iv) of claims 29, 32, and 38 allow them to bind to proteins with unlimited possible variations from SEQ ID NO:3 and 4, the prior art product (antibody) and methods of using them anticipate these claims. Note the cells are contacted with the antibodies; see paragraph [0128]. Claims 31 and 35 are included in this rejection as the antibody necessarily has an affinity for the extracellular region. It is noted that no particularly is recited in the claim, only that some affinity exist. Even if the antibody from Buck has a very weak affinity for this region, it is "an affinity" as recited in claims 31 and 35. Claim 33 is included in this rejection as Buck teaches selecting the cells which have bound to the antibody. Claims 30 and 34 are included as Buck explicitly teaches flow cytometry for the purification.

### ***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 38 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 10 of copending Application No. 11/622312. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claim encompass antibodies which bind to SEQ ID NO:3 or 4, or variants thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

June 26, 2008